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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,077	02/14/2001	Jonathan S. Stamler	1661 - CIP	9791

7590

07/02/2002

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/02/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/782,077

Applicant(s)

STAMLER et al.

Examiner

Pak, J.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

Art Unit: 1616

Claims 1-9 are pending in this application.

Claims 1-3 and 7-9 are generic to a plurality of disclosed patentably distinct species comprising therapeutic gases such as NOCl, N₂O₃ or H₂S. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Spector on 3/4/2002 a provisional election was made with traverse to prosecute the invention wherein the single disclosed species of therapeutic gas is NOCl, claims 1-4 and 7-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-6 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-4 and 7-9 will presently be examined to the extent that they read on the elected subject matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

Claims 1-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zapol.

Zapol (US 5,570,683) discloses treating various disorders related to pulmonary vasoconstriction, such as asthma, pulmonary hypertension and hypoxia (see the paragraph bridging columns 4 and 5) by administering in gas form nitric oxide or nitric oxide-releasing compound (column 4, lines 1-2). Known nitric oxide-releasing compounds are disclosed as those nitroso compounds characterized by an —NO moiety that is spontaneously released or otherwise transferred from the compound d under physiological conditions (column 5, lines 59-67). Phosphodiesterase inhibitor is administered prior to, during or immediately afterwards (column 4, lines 2-5).

While Zapol does not expressly disclose NOCl as the nitric oxide-releasing gas, one having ordinary skill in the art would have recognized from Zapol's full disclosure that a NOCl has the —NO moiety that would be suitable for Zapol's utility. Given the ready availability of NOCl one having ordinary skill in the art would have been motivated to utilize the same as Zapol's nitric oxide-releasing gas. Further use of N-acetylcysteine or ascorbate would have been fairly suggested from their known adjuvant therapeutic advantages, as acknowledged by applicant on specification page 11. Advantages of providing the antioxidant ascorbates are routinely recognized and practiced as an adjuvant therapy for variety of medical therapies. As for liquid HNO, Zapol provides the suggestion to use the same in aerosolized form (see column 5, lines 62-67; column 7, lines 35-67). Further, while Zapol does not explicitly disclose treating hypoxemia,

Art Unit: 1616

Zapol does teach treating hypoxia and other pulmonary vasoconstriction disorders, which are fairly suggestive of hypoxemia.

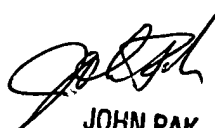
Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the teachings of the cited reference.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


JOHN PAK
PRIMARY EXAMINER
GROUP 1600